

## Indications for Use

510(k) Number: BK050016

Device Name: The GPS II Platelet Concentrate Separation Kit w/ Plasma Concentrator Accessory.

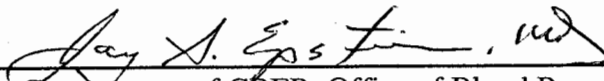
Indications For Use: The GPS II Platelet Concentrate Separation Kit w/ Plasma Concentrator Accessory is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) and concentrated platelet poor plasma (PPPc) from a small sample of blood at the patient's point of care. The PRP and PPPc can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

  
Concurrence of CBER, Office of Blood Research and Review

7/20/05